FEB 1 4 2003

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K024045**

Applicant information:

Date Prepared:	November 27, 2002
Name:	**CONTAMAC Ltd.**
Address	Bearwalden Business Park Saffron Walden Essex England CB11 4JX
Contact Person:	Robert McGregor
Phone number:	44-1799 542 000
US Agent:	Medvice Consulting, Inc. Martin Dalsing
Phone number	(970) 243-5490
Fax number	(970) 243-5501

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lenses, Soft Contact, Daily Wear
Trade Name:	**CONTAFLEX GM3 49% (acofilcon B) Spherical Soft Contact Lens for Daily Wear (clear and tinted, lathe-cut)**

Equivalent Devices:

The CONTAFLEX GM3 49% (acofilcon B) Spherical Soft Contact Lenses are substantially equivalent to the following predicate device

Predicate devices: "**BENZ-G3X**" manufactured/distributed by Benz Research and Development.
(hioxifilcon B)
510(k) number; **K964528**

"CONTAFLEX GM3 58%" manufactured by Contamac Ltd.
(acofilcon A)
510(k) number: **K023349**

Device Description:

The CONTAFLEX GM3 49% Spherical Soft Contact Lenses are fabricated from acofilcon B, which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

The non-ionic lens material, (acofilcon B) is a terpolymer based on high purity Glycerol Methacrylate 2,3-Dihydroxypropyl Methacrylate (GMA), with N-vinyl-2-pyrrolidone (NVP), methyl methacrylate (MMA), and 2-hydroxyethyl methacrylate (2-HEMA) and cross-linked with Diallyl Maleate (DAM). It consists of 51% acofilcon B and 49% water by weight when immersed in normal saline solution buffered with sodium bicarbonate. The lens is available in clear and with a blue visibility-handling tint, Color additive 'Reactive Blue 4' 21 CFR part 73.2121. The acofilcon B name has been adopted by the United States Adopted Names Council (USAN).

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The (acofilcon B) soft hydrophilic contact lens has a spherical back surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 49% water by weight. The physical properties of the lens are:

Refractive Index	1.52 (dry) 1.42 (hydrated)
Light Transmission	greater than 96%
Water Content	49 %
Specific Gravity	1.142 (hydrated)
Oxygen Permeability	15.89 X 10^{-11} (cm^2/sec) (ml O_2/ml x hPa @ 35°C), (revised Fatt method).

Intended Use:

The **CONTAFLEX GM3 49 (acofilcon B) Spherical** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity.
The lens may be disinfected using a chemical disinfecting system.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

Description of Safety:

A series of preclinical testing were performed to demonstrate the safety and effectiveness of the CONTAFLEX GM3 49 Soft Contact Lens material. The results of all testing demonstrated that the safety and effectiveness of the CONTAFLEX GM3 49 Soft Contact Lens is equivalent to the currently marketed Benz-G3X contact lens material, as well as the CONTAFLEX GM3 58. A summary of these results from the preclinical studies is presented below.

Toxicology:

In-Vitro Cytotoxicity: ISO 10993-5 was conducted in accordance with standards on test article. The test article meets the requirements of the Agarose Overlay Method.

Systemic Toxicity: The lens material meets the requirements of the systemic injection test and is considered non-toxic.

Acute Ocular Irritation: Acute ocular irritation test was performed and produced no ocular irritation.

Shelf Life

Shelf life requirements are satisfied via referencing rights granted to Contamac Ltd. for 510(k) 973597. The data presented supports substantial equivalence of this CONTAFLEX GM3 49 Soft Contact Lens material to the already marketed Benz-G3X.

Solution Compatibility

Studies were conducted on blue tinted lens material. Lenses were run through 30 cycles of cleaning and conditioning to establish the compatibility of the lens material with the recommended care regimen. The parameters of the base curve, back vertex power, total diameter and overall lens physical appearance were recorded prior to and upon completion of 30 cycles. Initial and final data were compared. There were no significant changes to lens parameters after 30 complete cycles.

Substantial Equivalence:

The CONTAFLEX GM3 49 Soft Contact Lens is substantial equivalent and *does not raise* different questions of safety and effectiveness than the predicate devices identified previously. The difference between the two devices is the USAN name.

The following table depicts the pre-clinical characteristics of the CONTAFLEX GM3 49 material, as compared to the predicate device.

Substantial Equivalence table

	Pre-Clinical equivalency / Device	CONTAFLEX GM3 49% (acofilcon B)	BENZ-G3X (hioxifilcon B)
1.)	**Intended Use**	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.
2.)	**Functionality**	After machining from the optical blank, the contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	After machining from the optical blank, the contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.
3.)	**Indications**	Daily wear, Soft (hydrophilic) contact lens	Daily wear, Soft (hydrophilic) contact lens
4.)	**Production Method**	Lathe-cut	Lathe-cut
5.)	**FDA Group #**	Group # 2 >50% Water, Nonionic Polymers	Group # 2 >50% Water, Nonionic Polymers
6.)	**USAN name**	Acofilcon B	Hioxifilcon B
7.)	**Water Content**	48.0%	48.0%
8.)	**Oxygen Permeability**	15.89 X 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).	16.40 X 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).
9.)	**Specific Gravity**	1.142	1.137

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 4 2003

Contamac, Ltd
C/O Martin Dalsing
Medvice Consulting, Inc.
623 Glacier Dr.
Grand Junction, CO 81503

Re: K024045
Trade/Device Name: CONTAFLEX GM3 49% (acofilcon B) Soft Contact Lens for Daily Wear (clear and tinted, lathe-cut)
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: November 27, 2002
Received: December 6, 2002

Dear Mr. Dalsing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Device Name: **CONTAFLEX GM3 49% (acofilcon B) Spherical Soft Contact Lens for Daily Wear (clear and tinted, lathe-cut)**

INDICATIONS FOR USE:

The **CONTAFLEX GM3 58 (acofilcon B) Spherical** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity.
The lens may be disinfected using a chemical disinfecting system.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

(PLEASE DO OT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use JS/ V
(Per 21 CFR 801.109)

or

Over-The-Counter Use ___

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K024045